

# CLAIMS

We claim:

1. An implantable tissue approximation device comprising:

- a) a supportive backing; and
- b) a plurality of attachment points extending from said backing.

2. The tissue approximation device of claim 1 wherein said backing has a shape in the form of a character selected from the group consisting of C, H, I, L, T, U, V,  $\Delta$ , and  $\cap$ .

3. The tissue approximation device of claim 1 wherein said backing has a shape substantially similar to any one of Figure 33A, Figure 33B, Figure 33C, Figure 33D, Figure 34, Figure 35, and Figure 36.

4. The tissue approximation device of claim 1 wherein the supportive backing has a discrete plate region useful in setting fragmented bones and a discrete tine region useful in suspending soft tissue wherein the supportive backing is thicker in the plate region than in the tine region.

5. The tissue approximation device of claim 4 wherein the plate region comprises at least one hole.

6. The tissue approximation device of claim 5 wherein the plate region is tineless.

7. The tissue approximation device of claim 4 wherein the plate region and the tine region are integral with the supportive backing.

8. The tissue approximation device of claim 1 wherein said backing is configured to be flexible.

5           9. The tissue approximation device of claim 8 wherein said backing defines a through-hole.

10           10. The tissue approximation device of claim 9 wherein said through-hole is slotted.

10           11. The tissue approximation device of claim 1 wherein said backing comprises porous material.

15           12. The tissue approximation device of claim 11 wherein said porous material comprises a mesh, net, or lattice.

            13. The tissue approximation device of claim 1 wherein said backing comprises a solid material.

20           14. The tissue approximation device of claim 1 wherein said attachment points are varied in density on said backing.

            15. The tissue approximation device of claim 1 wherein said attachment points are varied in length on said backing.

25           16. The tissue approximation device of claim 1 wherein said attachment points have shapes and directions selected from the group consisting of canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed

tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines.

5           17. The tissue approximation device of claim 1 wherein said attachment points each define a facet configured to be less than or equal to 90 degrees with a plane defined by tissue to be pierced by said attachment points.

10           18. The tissue approximation device of claim 1 wherein said backing further comprises a front side and a back side and wherein said attachment points extend from said front side.

15           19. The tissue approximation device of claim 18 further comprising a floor extending from said back side of said backing wherein said floor provides additional support and fixation to fractured bones to be repaired.

20           20. The tissue approximation device of claim 1 further comprising a post extending from a back side of said backing.

25           21. The tissue approximation device of claim 19 further comprising at least one screw hole disposed between the attachment points in said backing wherein said hole is sized to accommodate a fastener therethrough.

          22. The tissue approximation device of claim 20 wherein said post comprises a distal end and a proximal end, said proximal end being integrally attached to said backing.

          23. The tissue approximation device of claim 20 wherein said supportive backing is horseshoe shaped.

24. The tissue approximation device of claim 1 wherein the supportive backing is rigid.

5           25. The tissue approximation device of claim 24 wherein the supportive backing has a strength sufficient to set fragmented bones.

26. The tissue approximation device of claim 25 wherein the supportive backing defines a plurality of through-holes for receiving a fastener.

10           27. The tissue approximation device of claim 25 wherein the supportive backing comprises an anchoring post.

15           28. The tissue approximation device of claim 22 wherein said post further comprises an integral locking device.

20           29. The tissue approximation device of claim 28 wherein said integral locking device is selected from the group consisting of collars, partial collars, tabs, barbs, sub-cortical wings and any combinations thereof.

30. The tissue approximation device of claim 20 wherein said post is threaded.

25           31. The tissue approximation device of claim 1 wherein said backing further defines a hole configured to receive a fastener.

32. The tissue approximation device of claim 31 wherein said fastener is selected from the group consisting of pins, rivets, nails, and screws.

5 33. The tissue approximation device of claim 27 wherein said post is configured to be secured to a facial bone via an adhesive.

34. The tissue approximation device of claim 33 wherein said adhesive is selected from the group consisting of cyanoacrylate, fibrin, and methylmethacrylate.

10 35. The tissue approximation device of claim 20 wherein said post comprises a hook.

36. The tissue approximation device of claim 20 wherein said post extends from said backing at a predetermined angle.

15 37. The tissue approximation device of claim 20 wherein said post comprises a distal end configured to expand radially about an axis defined by said post.

20 38. The tissue approximation device of claim 20 wherein said post further comprises a latch pivotally disposed between post members.

39. The tissue approximation device of claim 38 wherein said latch is biased to extend angularly away from said post members.

25 40. The tissue approximation device of claim 24 wherein the supportive backing has a thickness greater than 1.0 mm.

41. The tissue approximation device of claim 20 wherein said post is configured to be received by a hole defined in a facial bone.

5 42. The tissue approximation device of claim 41 wherein said hole is angularly defined in said facial bone.

43. The tissue approximation device of claim 41 wherein said hole is defined to have a plurality of concentric grooves.

10 44. The tissue approximation device of claim 1 further comprising at least two posts extending from said backing.

45. The tissue approximation device of claim 44 wherein said posts are adjacent to one another.

15 46. The tissue approximation device of claim 1 wherein said device comprises a material selected from the group consisting of biodegradable and biological materials.

20 47. The tissue approximation device of claim 46 wherein said biological material comprises one or more materials selected from the group consisting of collagen, hydroxyapatite from natural sources, hydroxyapatite from synthetic sources, bone graft, and any polymerized versions or composites thereof.

25 48. The tissue approximation device of claim 1 wherein said backing is curved.

49. The tissue approximation device of claim 1 wherein said device is configured such that it is shapeable intra-operatively for use in a patient's body.

50. The tissue approximation device of claim 18 wherein said back side of said backing is concave.

51. The tissue approximation device of claim 1 further comprising a rigid fracture plate connected to said supportive backing via an extension member.

52. The tissue approximation device of claim 51 wherein said extension member is thread-like.

53. The tissue approximation device of claim 51 wherein said fracture plate includes at least one bone anchor to secure the plate to a fracture site.

54. The tissue approximation device of claim 1 wherein said device comprises a number of through-holes of equal spacing.

55. The tissue approximation device of claim 1 wherein said device comprises at least one therapeutic agent.

56. The tissue approximation device of claim 55 wherein said device is impregnated with said at least one therapeutic agent.

57. The tissue approximation device of claim 55 wherein said device is coated with said at least one therapeutic agent.

58. The tissue approximation device of claim 57 wherein said at least one therapeutic agent is selected from the group consisting of proteins, pharmaceuticals, genetic material.

5 59. The tissue approximation device of claim 1 further comprising at least one bone anchor joined to said backing via a narrow extension member.

60. The tissue approximation device of claim 59 wherein said extension member is thread-like.

10 61. The tissue approximation device of claim 60 further comprising a knob rotatably connected to said anchor and extending therefrom, said knob connected to a proximal end of said extension member such that rotation of said knob adjusts the length of said extension member.

15 62. A method for repairing a fracture site comprising:  
 a) lifting tissue off the fracture site;  
 b) affixing an implantable tissue approximation device to said fracture site such that the fracture is reduced and set, said device comprising a supportive backing  
 20 and a plurality of attachment points extending from said backing; and  
 c) hanging said tissue on said plurality of attachment points.

63. The method of claim 62 wherein said tissue comprises cheek tissue.

25 64. The method of claim 62 wherein said device further comprises a flat floor perpendicularly extending from said supportive backing.



65. The method of claim 62 wherein said fracture site comprises bones of the maxilla.

5 66. The method of claim 62 wherein said approximation device in said step b) is affixed to said fracture site via a fastener.

67. The method of claim 62 wherein said approximation device in said step b) is affixed to said fracture site via an anchoring post.

10 68. A method of tissue approximation in tissue suspension surgical procedures comprising:

a) securing an implantable tissue approximation device to an underlying bone, said approximation device comprising a supportive backing and at least one attachment point extending from said backing;

15 b) mobilizing tissue or layer of tissue to be approximated towards said approximation device; and

c) setting said tissue or layer of tissue onto said approximation device.

20 69. The method of claim 68 wherein said tissue or layer of tissue comprises cheek tissue.

70. The method of claim 68 wherein said tissue or layer of tissue in said step c) is set on said approximation device via a plurality of attachment points.

25 71. The method of claim 68 wherein said bone is a bone of the maxilla.

72. The method of claim 68 wherein said approximation device in said step a) is secured to said bone via at least one fastener.

73. The method of claim 68 wherein said approximation device in said step a) is secured to said bone via an anchoring post.

74. The method of claim 68 wherein said step a) further comprises readjusting a position of said approximation device by manipulating at least one protrusion integrally extending from said backing.

75. A fracture fixation fastener comprising:  
a solid body having a distal end and a proximal end; and  
at least one tine extending from the proximal end, said tine terminating in a sharp point.

76. The fracture fixation fastener of claim 75 wherein at least a portion of the body is threaded.

77. A fracture fixation system for surgical procedures comprising:  
a plate useful in setting fractured bones into a selected position, said plate having at least one hole therethrough; and  
at least one fastener adapted to secure said plate to said fractured bones wherein at least one of said fastener and said plate comprises at least one tine extending therefrom and said tine terminating in a sharp point.

78. The fracture fixation system of claim 77 wherein only said at least one fastener comprises said at least one tine.

79. The fracture fixation system of claim 78 wherein said at least one fastener has a self-tapping configuration.

80. A fracture fixation system for surgical procedures comprising:  
 a plate useful in setting fractured bones into a selected position, said plate  
 having at least one through-hole;  
 at least one fastener adapted to secure said plate to said fractured bones, said  
 5 fastener having a body and an enlarged head; and  
 at least one spacer secured between said plate and said enlarged head of said  
 fastener when said plate is secured to said fractured bones, said at least one spacer  
 having a discrete tissue attachment area which remains uncovered by said enlarged  
 head when said plate is secured to said fractured bones and wherein said discrete  
 10 tissue attachment area has at least one tine extending therefrom useful in soft tissue  
 fixation.

81. The fracture fixation system of claim 80 wherein said spacer is washer-  
 shaped and defines an aperture configured to receive said body of said at least one  
 15 fastener when said plate is secured to said fractured bones.

82. The fracture fixation system of claim 81 comprising a plurality said  
 fasteners and a plurality of said spacers and wherein said plate contains a plurality of  
 through-holes.

83. The fracture fixation system of claim 82 wherein said plate is tineless.

84. The tissue approximation device of claim 53 wherein said at least one  
 bone anchor is selected from the group consisting of pins, tacks, rivets, screws,  
 25 expanders, and posts.

85. The tissue approximation device of claim 51 wherein the extension  
 member is made of a different material than said supportive backing.

86. The tissue approximation device of claim 51 wherein the extension member is made of a suture-like material.

5           87. The tissue approximation device of claim 59 wherein said at least one bone anchor is selected from the group consisting of pins, tacks, rivets, screws, expanders, and posts.

10           88. The tissue approximation device of claim 59 wherein the extension member is made of a different material than said supportive backing.

          89. The tissue approximation device of claim 59 wherein the extension member is made of a suture-like material.

15           90. The tissue approximation device of claim 53 wherein said at least one bone anchor is integral with the fracture plate.

          91. The fracture fixation fastener of claim 75 wherein said body has a shape selected from the group consisting of pins, tacks, rivets, screws, expanders, and posts.